

REMARKS

A first non-final Office Action mailed July 15, 2004 has been received and carefully reviewed. Claims 1-35 are pending in the application. Original claims 1-35 have been rejected. Claims 1, 6, 11, 13, 14, 19, 24, and 30 have been amended. Reconsideration of the application as amended and withdrawal of the present rejections are respectfully requested in view of the amendments to the claims and the following remarks.

The Examiner objected to the drawings because passive and tined fixation features recited in claims 11 and 13 are not shown in drawings. Claims 11 and 13 have been amended in a manner which renders the drawing objection moot.

Claims 11 and 13 stand rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the enablement requirement. Claims 11 and 13 have been amended in a manner which renders this rejection moot. However, Applicant's specification incorporates by reference several US patents and applications that disclose numerous embodiments of tined and passive fixation implementations. As such, original claims 11 and 13 comply with 35 U.S.C. § 112, first paragraph, and Applicant reserves the opportunity to claim these features at a later time or in a subsequent continuing application.

Claims 1, 3, 6, 8, 12, 14, 16, 19, 21, 30, 31, and 33 stand rejected under 35 U.S.C. § 102(b) as being anticipated by *Helland et al.* (U.S. Patent No. 5,545,201). *Helland* discloses a bipolar active fixation lead having a helix 44 defining an outer electrode 46, an intermediate insulator 48, and an outer electrode 50, as shown in Figures 3-5 of *Helland*. *Helland* further teaches that the outer electrode 50 is preferably spaced from the exposed portion of the central electrode 46 via the intermediate insulator 48 so that the outer and central electrodes 50, 46 operate as a bipolar electrode pair. *Helland* teaches that the intermediate insulator may be formed of polyurethane, polytetrafluoroethylene (PTFE), silicone rubber, or Tefzel material. See column 4, lines 26-30 of *Helland*.

To anticipate a claim, the asserted reference must teach every element of the claim. A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. The identical invention must be shown in as complete detail as is contained in the claim. All claim elements and their limitations must be found in the prior art reference to maintain a rejection based on 35 U.S.C. §102.

Applicant's claims 1, 3, 6, 8, 12, 14, 16, 19, 21, 30, 31, and 33, as amended, recite, in various forms, a fluoropolymer coating or sleeve provided on some or all of an active fixation arrangement or electrode sufficient in coverage to inhibit exit block development. As is described in Applicant's specification at page 6, lines 25-27 and elsewhere, for example, exit block is a condition where fibrotic tissue encapsulates a lead's electrode, such that the encapsulation drives up pacing thresholds, which can lead to system failure.

Helland fails to expressly teach a fluoropolymer coating or sleeve provided on some or all of an active fixation arrangement or electrode sufficient in coverage to inhibit exit block development. *Helland* further fails to inherently teach this feature of Applicant's claims as amended. *Helland* wholly fails to teach use of its intermediate separator in the context of exit block. Rather, *Helland* teaches use of various polymeric materials as an electrical insulator on a central electrode of a helix to separate the central electrode from an outer electrode of the helix, which is necessary to form a bipolar electrode pair.

Clearly, *Helland* fails to teach the identical invention contemplated in Applicant's claims 1, 3, 6, 8, 12, 14, 16, 19, 21, 30, 31, and 33. *Helland* further fails to teach the invention in as complete detail as is contained in Applicant's claims 1, 3, 6, 8, 12, 14, 16, 19, 21, 30, 31, and 33. Accordingly, Applicant's claims 1, 3, 6, 8, 12, 14, 16, 19, 21, 30, 31, and 33 are not anticipated by *Helland*.

Claims 2, 4, 7, 9, 15, 17, 20, 22, 32, and 34 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over *Helland et al.* (U.S. Patent No. 5,545,201) in view of *Carson* (U.S. Patent No. 5,931,862).

To establish *prima facie* obviousness of Applicant's claimed invention, the Examiner has the burden of proving that three basic criteria are met. First, there must be some suggestion or motivation to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art references must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on Applicant's disclosure. All three of these criteria must be met in order to support a finding of *prima facie* obviousness of a claimed invention (*see, e.g.*, MPEP § 2142).

Carson discloses a sheath of ePTFE on the outside of a medical lead. As shown in Figures 2 and 3, the ePTFE covering 10 of lead 12 extends along the lead body 14, a defibrillation electrode 16, and a shank 16 of a distal helical pacing electrode 20. *Carson* further teaches that portions of lead 12 not covered by covering 10 include the distal pacing electrode 20, which is shown to include a helix or tine fixation element. *See Carson*, column 4, lines 34-36.

Because *Carson* specifically teaches against covering distal helical pacing electrode 20 with ePTFE, it is unclear how the combination of *Helland* and *Carson* could be combined so as to arrive at Applicant's claimed subject matter. The asserted combination fails to teach all limitations of claims 2, 4, 7, 9, 15, 17, 20, 22, 32 and 34, for reasons discussed above.

Applicant respectfully asserts that the combination of *Helland* and *Carson* lacks the requisite motivation to support their combination in a manner suggested by the Examiner. For example, *Helland* is silent on use of a fluoropolymer coating or sleeve provided on some or all of an active fixation arrangement or electrode sufficient in coverage to inhibit exit block development, and *Carson* specifically teaches against

covering such an active fixation arrangement or electrode with a fluoropolymer (e.g., ePTFE). One skilled in the art would clearly not be motivated to combine the reference teachings in the manner suggested by the Examiner, particularly in view of *Carson's* explicit teaching against such a combination. Moreover, the Examiner must show reasons that the skilled artisan, confronted with the same problems as the inventor and with no knowledge of the claimed invention, would select the elements from the cited prior art references for combination in the manner claimed. *In re Rouffet*, 149 F.3d 1350 (Fed. Cir. 1998). A reading of the asserted references makes clear that the problems addressed by *Helland* and *Carson* are significantly different from that addressed in Applicant's disclosure.

Further, the asserted combination fails to provide a reasonable expectation that one skilled in the art could successfully arrive at Applicant's claimed apparatus. *Helland's* fluoropolymer element is an electrical insulator disposed between two electrode elements, and *Carson* teaches against use of such a fluoropolymer element on the electrode configuration taught in *Helland*. It is a requirement that actual evidence of a suggestion, teaching or motivation to combine prior art references be shown, and that this evidence be "clear and particular." *In re Dembiczak*, 50 USPQ2d 1614 (Fed. Cir. 1999). Broad conclusory statements regarding the teaching of references, standing alone, are not evidence. *Id.*

For at least these reasons, claims 2, 4, 7, 9, 15, 17, 20, 22, 32 and 34 are patentable over the combination of *Helland* and *Carson*.

Claim 11 stands rejected under 35 U.S.C. § 103(a) as being unpatentable over *Rockland et al.* (U.S. Patent No. 4,010,758) in view of *Helland et al.* (U.S. Patent No. 5,545,201). Claim 13 stands rejected under 35 U.S.C. § 103(a) as being unpatentable over *Altman et al.* (U.S. Patent No. 5,845,396) in view of *Helland et al.* (U.S. Patent No. 5,545,201). Claims 5, 10, 18, 23 and 35 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over *Helland et al.* (U.S. Patent No. 5,545,201) in view of *Stokes et al.* (H356). Claims 24, 25 and 27 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over *Dutcher et al.* (U.S. Patent No. 4,357,946) in view of *Helland et al.*

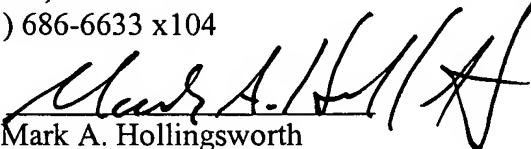
(U.S. Patent No. 5,545,201). Claims 26 and 28 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over *Dutcher et al.* (U.S. Patent No. 4,357,946) in view of *Helland et al.* (U.S. Patent No. 5,545,201) as applies to claim 24 above in further view of *Carson* (U.S. Patent No. 5,931,862). Claim 29 stands rejected under 35 U.S.C. § 103(a) as being unpatentable over *Dutcher et al.* (U.S. Patent No. 4,357,946) in view of *Helland et al.* (U.S. Patent No. 5,545,201) as applied to claim 24 above in further view of *Stokes et al.* (H356).

Each of the above-listed obviousness rejections rely on the teaching of *Helland*. Applicant asserts that these references when combined with *Helland* fail to render the claims listed above unpatentable. In view of the arguments made hereinabove, Applicant believes it unnecessary to address each of the rejections listed in the preceding paragraph. It is to be understood, however, that Applicant does not acquiesce to the Examiner's characterization of the asserted art or Applicant's claimed subject matter, nor of the Examiner's application of the asserted art combinations to Applicant's claimed subject matter. Applicant reserves the right to address in detail the Examiner's characterizations and rejections of the claims listed immediately above in future prosecution.

It is believed that the pending claims as amended are in condition for allowance and notification to that effect is respectfully requested. The Examiner is invited to contact Applicant's Representatives, at the below-listed telephone number, if there are any questions regarding the above new claims or if prosecution of this application may be assisted thereby.

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